

## R E M A R K S

Claims 33 and 47 - 48 are in this application. Claims 1-32 and 34- 46 have been cancelled. Claim 33 has been amended and Claims 47 and 48 have been added.

Applicants preserve all rights to file one or more divisional applications directed to any subject matter disclosed in this application and not presently claimed.

Support for Claim 47 is found in original Claim 33. Support for Claim 48 is found, *inter alia*, in Examples 4A and 4B.

According to the Advisory Action of July 27, 2005, the cancellation of claims 1, 2,4-7, 38, 43, 44 and 46 would obviate the rejection under 35 USC 102(a) as being anticipated by De Souza (U.S. Patent 6,514,986). These claims have been cancelled.

According to the Advisory Action of July 27, 2005, the cancellation of 1, 2,4-7, 38, 43, 44 and 46 would obviate the rejection under 35 USC 102(e) as being anticipated by Patel I (2003/0207908) or Patel II (6,750,224). These claims have been cancelled.

According to the Advisory Action of July 27, 2005, the cancellation of 1, 2,4-7, 38, 43, 44 and 46 would obviate the rejection under 35 USC 102(a) as being anticipated by De Souza (WO 01/85095). These claims have been cancelled.

According to the Advisory Action of July 27, 2005, the cancellation of 1, 2,4-6, 38, 43, 44 and 46 would obviate the rejection under 35 USC 102(b) as being anticipated by Patel III (WO 00/68229). These claims have been cancelled.

According to the Official Action, claims 1-7, 22-26, 33, 38 and 43-46 as being obvious over WO 00/68229 in view of Kwan. Applicants respectfully traverse this rejection.

Claims 1-7, 21-26 and 43-46 have been cancelled.

The standard test used to establish *prima facie* obviousness is the test set out by the Supreme Court in *Graham v. John Deere* (383 US 1, 148 USPQ 459 (1966)). To determine whether a claim is *prima facie* obvious:

- 1) the scope and content of the prior art are to be determined;
- 2) the differences between the prior art and the claims at issue are to be ascertained; and
- 3) the level of ordinary skill in the pertinent art resolved.

In addition, according to MPEP 2141, citing *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n. 5 (Fed. Cir. 1986), when applying 35 USC 103, the following tenets of patent law must be adhered to:

- 1) the claimed invention must be considered as a whole;
- 2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; and
- 3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention.

Reasonable expectation of success is the standard with which obviousness is determined. *In re Merck & Co., Inc.*, 800 F.2d109, 231 USPQ 375 (Fed. Cir. 1986).

The reason, suggestion or motivation to combine references may be found explicitly or implicitly. While the references need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability must be clear and particular. *Ruiz v. A.B. Chance Co.*, 57 USPQ2d 1161 (Fed. Cir. 2000).

Based on these requirements it is clear that the process of claims 33, 47 and 48 is not obvious because considering Kwan and WO 00/68229 as a whole, the references do not suggest the desirability and thus the obviousness of making the combination. Neither reference alone or in combination describes the need for enhancing the optical purity of of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt and neither reference alone or in combination describes or suggests the steps of claims 33, 47 and 48. Therefore, it is respectfully requested that this rejection be withdrawn.

According to the Official Action, Claims 1-7, 21-26, 33, 38, and 43-46 are rejected under 35 USC 103(a) as being unpatentable over Ishikawa (U.S. Patent 4,399,134) or Hashimoto or Morita or Kido in view of Berge and/or Fujisawa and further in view of Kwan (U.S. Patent 5,200,558). Applicants respectfully traverse this rejection.

As noted above, Claims 1-7, 21-26, 38 and 43-46 have been cancelled.

Applicants' respectfully disagree with the Examiner's statement "[g]uided by the teaching of Berge and Fujisawa, one of ordinary skill in the art would be motivated to prepare the arginine salt of the piperidiny-benzoquinolizine compound of Ishikawa to arrive at the instant invention."

Applicants respectfully disagree that the claimed invention is obvious based on the standards described above. There is no suggestion in the combination of references to prepare the compounds as claim. Table III on page 5 of Berge lists 40 different salt-forming agents and a large number of antimicrobials. There is no suggestion to select arginine as the salt and in fact, fluoroquinolones are not even included in the table. Berge does not disclose benzoquinolizine compounds. The compounds of Fujisawa and Kwan differ in both their structure and their properties and Ishikawa does not include nor suggest that amino acid salts of benzoquinolizine compounds can be prepared by the process claimed in this application. The suggestion to do what applicants' have done is not found in the prior art and one skilled in the art considering the

cited references would not have a reasonable expectation that the claimed compounds could be prepared by the process claimed in this application.

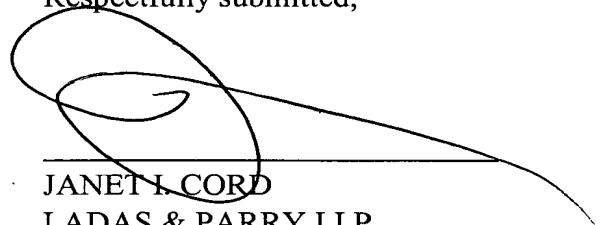
None of the references either individually or in combination disclose or suggest the claimed method and thus, Claims 33, 47 and 48 are not obvious.

It is respectfully requested that this rejection be withdrawn.

All rights to file one or more continuation, divisional and continuation-in-part applications directed to any subject matter disclosed in this application including subject matter previously claimed and not presently claimed is preserved.

It is respectfully submitted that this application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,



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